UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/781,296	01/13/97	HARLEY J	OMRF161

PATREA L PABST
ARNALL GOLDEN & GREGORY
2800 ONE ATLANTIC CENTER
1201 W PEACHTREE STREET
ATLANTA GA 30309-3450

HM12/0104

EXAMINER	
ZEMAN, M	
ART UNIT	**PAPER NUMBER**
1631	30

DATE MAILED: 01/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)

1- File Copy

Office Action Summary

Application No.	Applicant(s)
08/781,296	Harley et al.
Examiner	**Group Art Unit**
Mary K Zeman	1631

☒ Responsive to communication(s) filed on *Oct 19, 1999*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *THREE* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *27-40* is/are pending in the application.

Of the above, claim(s) *30-40* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *27-29* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1631.

The response filed 10/18/99 has been considered, and the amendment has been entered.

Election/Restriction

Applicant has elected the inveniton of Group II claims 27 and 28 and the species of SEQ ID NO:27. In addition applicant has submitted new claims 29-40.

However, claims 30 to 40 are directed to an inveniton independent and distinct from that of claims 27 and 28. In particular, claims 30-34 appear to be directed to peptides, not immunogenic compositions, which peptides are intended for use in assays such as that set forth in claims 35-40. The peptides of claims 30-34 are in a materially different form from the immunogenic compositions comprised of the peptides. Similarly a method for determining likelihood of developing autoimmunity wherein an immunoassay is involved is clearly distinct from a method of acheiving tolerance.

Claims 30 to 40 are withdrawn from consideration.

Claim Rejections - 35 USC § 112

Claims 27-29 are rejected under 35 USC §112, second paragraph as being vague and indefinite.

The claims recite "an immunogenic composition comprising a peptide" which could reasonably be read as a mixture of a specific peptide with other components, however, the specification appears to include within the scope of said immunogenic compositions those in which the specifically recited peptide is attached to a carrier moelcule. Moreover, a composition is a mixture of compounds which compounds are not covalently attached to one another. Thus, one would not reasonably expect that covalent complexes of the recited peptides with carrier molecules would be within the scope of the claims. In addition, it is unclear from the claims and specification whether or not combinations is intended to embrace mixtures or covalently attached polymers of the specifically recited peptides.

Claims 28 and 29 are rejected under 35 USC §112 first paragraph. Any given specific peptide administered prior to EBV infection might elicit tolerance to EBV effects associated with that particular peptide. However, there is nothing to suggest that tolerance to an "epitope" of EBV confers tolerance to all epitopes.

The data discussed in the declaration of record by Dr Harley seems to indicate the induction of tolerance to a particular peptide when the peptide is used for immunization under particular conditions or dosing schedules. The tolerance was measured by the lack of subsequent production of the relevant autoantibody to that peptide. There is no indication that immunization with one peptide tolerizes the subject to ALL of the potential autoantibody incuding epitopes on

the EBNA molecule. The claims are not limited to particular dosing schedules or the conditions set forth in the declaration, which appear to have a material effect upon the induction of tolerance to that antigen. Nor are the claims limited to inducing tolerance to solely the administered epitope.

The specification does not set forth any direct correlation between the administration of the elected composition, and the development of tolerance to EBV associated imune responses. While antibodies to a particular epitope could be common in a patient with SLE, there is no indication that the administration of a single epitope,would have any effect upon the clinical course of the disease, whether it be preventing the development of that disease, or the treatment of that disease. It is also not clear that the administration of the claimed composition would prevent the development of antibodies to other autoantigen epitopes when challenged with native virus. If there are so many epitopes, as set forth in claim 27, it is possible that despite the vaccine with one epitope, the patient may develop antibodies to the a different epitioe upon challenge with native virus. Therefore, the specification is not enabling for the invention as it is now claimed.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

As has been set forth in previous Office Actions the claims are entitled to the filing date of the provisional application .

The peptide of SEQ ID NO:27 is free of the art, however, in view of the ambiguity of the claims any peptide or polypeptide containing SEQ ID NO: 27 is viewed as within the scope of the claim.

Claim 27 is rejected under 35 USC §102 (e) as being clearly anticipated by Middeldorp (US 5, 965,353). Middeldorp discloses SEQ ID NO: 1 which contains applicant's SEQ ID NO: 27 as being an immunogenic fragment. In addition, Middeldorp discloses SEQ ID NO:6 which corresponds exactly to applicant's SEQ ID NO: 24.

Claim 27 is rejected under 35 USC §102(b) as being clearly anticipated by Middeldorp (WO 94/06912).

Middeldorp (WO 94/06912) discloses SEQ ID NO: 1 which contains applicant's SEQ ID NO: 27 as being an immunogenic fragment. In addition, Middeldorp discloses SEQ ID NO:6 which corresponds exactly to applicant's SEQ ID NO: 24. Middeldorp specifically discloses the use of peptides or fragments of the peptides for use in treating EBV-related diseases (see page 9, third paragraph and page 11 first full paragraph).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Middeldorp (US Patent 5,965,353).

Claims 28 and 29 are rejected as being obvious over Middeldorp in view of the suggestion at column 4, lines 59-64 of Middeldorp to employ the recited peptides in the treatment of EBV-related disease. In this suggestion, pharmaceutical preparations of the peptides are contemplated. Middeldorp specifically includes the use of fragments of the peptides he discloses at column 5 line 36 to column 6 line 15. The fragments to be used must contain at least one epitope. By immunizing a subject with a peptide, one tolerizes the subject to the effects of said peptide. Therefore, the suggestion of Middeldorp to immunize with peptides or fragments of SEQ ID Nos 1 and 6, renders the claimed invention *prima facie* obvious, barring evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner

can be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

The fax number for this Art Unit is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

mkz
January 3, 2000

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600